UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,015	02/12/2001	Edmund Y.M. Chein	00115P002D	2156

8791 7590 05/03/2002

BLAKELY SOKOLOFF TAYLOR & ZAFMAN
12400 WILSHIRE BOULEVARD, SEVENTH FLOOR
LOS ANGELES, CA 90025

EXAMINER	
GUPTA, ANISH	

ART UNIT	PAPER NUMBER
1653	7

DATE MAILED: 05/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/782,015	CHEIN, EDMUND Y.M.	
	Examin r	Art Unit	
	Anish Gupta	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 10-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons set forth in the previous office action and the reasons set forth below.

For the rejection with respect to "predetermined physiological levels," Applicants argue that they have provided "Applicant's opinion (emphasis added) on the optimum levels of various hormones of both sexes in the second and third decade at the time the Application was filed." Thus the claims are definite with respect to the terminology.

For the rejection with respect to the "kit," Applicants argue "while these minor aspects of method of use are variations on detail of administration the composition of the claims; the claims as written are sufficiently definite to describe the invention for the purpose of patenting."

Applicant's arguments filed 2-21-02 have been fully considered but they are not persuasive.

Applicants opinion cannot be used to set forth a definition for a term that requires set numerical values. In determining the physiological data, an objective criteria needs furnished for definiteness. Applicants have provided only a subjective criteria. One skilled in the art could not determine if the physiological levels intended by the claims are limited to "Applicant's opinion" or the opinion of some else in the art.

With respect to kits, Applicants have not provided any reasonable basis why the claim is not indefinite. It is unclear from the claim what aspect renders the claim a "kit." Applicants claims do not set forth a single item that are normally associated with a kit.

Rejections are maintained.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 10-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Danielov et al. (US5885974).

Applicants have argued that the reference of Danielov et al. provides composition useful in treatment of various skin and scalp disease using a topical formulation comprising somatotropin, luteinizing hormone, and thyrotropic hormone. Applicants state that from the combination of the

claims and the specification the hormone measurements of the instant invention are those in the blood stream. The reference, according to Applicants, "does not disclose adjusting hormone levels in the bloodstream of a human using various combination of kits and hormones." Thus the reference does not render obvious the claimed invention since the reference "fails to teach, suggest or motivate towards 'replenishing hormone levels to predetermined physiological levels' and 'physiological levels' associated with the second and third decade of an average human subject."

Applicant's arguments filed 2-21-02 have been fully considered but they are not persuasive.

First, the claims do not make a distinction between topical or any other form. The claims teach a composition that comprises human growth hormone in combination with another hormone. In any respect, the reference repeatedly states that the kit can be used in parenteral form for the treatment of trauma or shock (see col. 5, lines 15-17). Thus, the formulation of the reference is not limited to the topical administration. Further, the reference teach that the compositions results "in the resumption of normal cell metabolism" and have concentration that are within the claimed range (see claim 4). Thus, the composition, since it is given parenterally and in the claimed concentration range, the physiological concentration would necessarily be achieved.

Rejection is maintained.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 10-17 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26-34 of U.S. Patent No. 5,855,920. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons set forth in the previous office action and the reasons set forth below.

Applicants argue that claims of the instant application are drawn to hormone regiment that are useful in treating symptoms associated with MS. The US Patent, on the other hand, is drawn to a method of increasing a life expectancy and life span by determining the level of human growth hormone and at least two supplemented hormones. Thus, "it would not be obvious to one of ordinary skill in the art to treat symptoms associated with multiple sclerosis with the kit and composition of the '920 patent."

Applicant's arguments filed 2-21-02 have been fully considered but they are not persuasive.

The language of symptoms associated with multiple sclerosis is an intended use limitation and intended use or field of use. Such language will not limit the scope of a claim. Moreover, where the claimed and prior art products are identical or substantially identical in structure or composition, a prima facie case of either anticipation or obviousness has been established. In re Best, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie

case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, *supra*.

Here, the reference teach a composition, similar to the claimed invention, with human growth hormone and two other hormones, similar to the claimed invention. The concentration disclosed for the hormone are the the same as the concentration claimed in the instant application (see claim 31 of the US Patent and 15 of the instant application). Further note that the hormones are administered in a amount "sufficient in establishing a regimen for the replenishment of said human growth hormone and at lease two of said supplemented hormones to predetermined physiological levels." Thus the claimed composition and composition disclosed in the US Patent are sufficient obvious over one another.

Rejection is maintained.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can normally be reached on (703)308-2923. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Anish Gupta

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600